Controlled Substances and Dangerous Drugs Compliance: Building Blocks for Success

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Expecting compliance without a proper foundation is like...

Building a house with a deck of cards!
In this presentation

Why compliance matters

The law

Responsibilities of the Registrants

Ongoing Training
The Federal and State Regulations are designed to operate within a closed system of distribution for the protection of public health safety to prevent the diversion of controlled substances into the illicit market.

Drug diversion is the illegal distribution or abuse/use of prescription drugs away from the intended end user or a legitimate source.

Each Registrant must do what the law requires so that the drugs stay in the closed system of distribution and the drugs are not diverted onto the streets!
Drug Diversion: It would never happen here!

99% of the time Diversion happens from the inside.

The #1 reason - People’s life circumstances change in an instant

Diversion Case Review
August 30, 2018
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Drug Enforcement Administration
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Record settlement reached in University of Michigan hospital drug diversion civil penalty case

DETOIT - The Drug Enforcement Administration and United States Attorney's Office for the Eastern District of Michigan today announced that the University of Michigan Health System has agreed to pay the United States $4.3 million as part of a settlement resolving allegations that UMHS violated certain provisions of the Controlled Substances Act, 21 U.S.C. §§ 801-904. The settlement, which is civil in nature, resulted from a years-long Drug Enforcement Administration investigation of UMHS's handling of controlled substances. It is the nation's largest settlement of its kind involving allegations of drug diversion at a hospital.

DEA began its investigation after two tragic incidents occurred in December 2013 involving two UMHS employees—a nurse and an anesthesiology resident. Both overdosed on opioids, including fentanyl, at a UMHS facility. The nurse's overdose was fatal.

RALEIGH, N.C.— A former Fuquay-Varina nurse was sentenced today to 28 months for entering the dispensing room with saline solution instead of a narcotic and replacing the drug with a clear vial and took a cut from the locked narcotics supply cabinet and

For Immediate Release

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https://emorywheel.com/drugs-scams-costs-university-health-system-millions/
The Law: Regulatory Requirements

Federal Requirements (DEA Registrants only) – 21 CFR Part 1300 to end

State Regulations (All Registrants) – O.C.G.A Title 16, Chapter 13, Articles 1-3, O.C.G. A Rule 480-7-04

Each licensee is responsible for knowing and complying with all the regulations required by the license.
Researcher Responsibility:
Keeping drugs inside the closed system of distribution
Drug Accountability
Know the Laws & Penalties
Understand ALL the Regulations
Proper Recordkeeping
Drug Accountability
Due Diligence
Policy
Procedures
Reporting
Registration
Security Requirements

100% Compliance
Future Training Topics:

• Obtaining Proper Licensing – Pre-Registration Assistance & Proper Security
• What do I do once I receive my license? Setting up my drug binders
• What’s a controlled substance and what’s a dangerous drug?
• How do I conduct an Inventory? (Initial, Biennial or Annual)
• Ordering and Receiving Drugs Properly
• Current Use Forms. Which forms do I use?
• Disposing of Drug Properly
• Maintaining Drug Accountability
• Theft/Loss Reporting? It is a BIG Deal!
• Who do these controlled substances belong to? Abandoned drugs
• Conducting Self Inspections
• What happens when I retire or leave Emory?
Register for Training Sessions here:

Meeting Registration - Zoom

Managing Controlled Substances & Dangerous Drugs in Research

You can choose to attend one or more of the following sessions.

- Nov 8, 2023 12:00 PM
- Dec 13, 2023 12:00 PM
- Jan 10, 2024 12:00 PM
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Thank you! Any Questions?